

*Sub-
G1*

32. The method according to claim 15 wherein recombinant LH, native LHRH or LHRH agonist are given to avoid hyperstimulation syndrome.-- *administered.*

REMARKS

With entry of this amendment, claims 15-32 are pending. Support for the new claims can be found in the originally filed claims and throughout the specification. No new matter has been added. Reconsideration is requested.

The Examiner requested a revised 1449 form which included the names of the authors. A revised 1449 form is included herewith. The Examiner objected to the specification as lacking a brief description of the drawing. The specification has been amended to include such.

The Examiner rejected claims 3, 4, and 6-14 under 35 USC § 112, second paragraph, as being indefinite. The Examiner indicated that the expression beginning with "preferably" in claims 4, 6, 7, and 10 is improper. This expression is not found in the newly entered claims. In claim 3, the Examiner considered the phrase "substances other than exogenous gonadotrophins" to be vague and indefinite. Replacement claim 17 recites substances which would be understood to be included by persons of skill in the art, as recited on page 4, line 10 of the specification.

The limitation "rec. LH" as recited in claims 9 and 11 was indicated to be indefinite and is not found in the presently pending claims.

Claims 1-14 were rejected under 35 USC § 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al. Enclosed is the Declaration of Klaus Diedrich, a named inventor on the present application and an author of the Felderbaum et al. reference cited in the § 103(a) rejection. The Declaration establishes that the coauthors on the Felderbaum publication who are not named inventors on the present application did not have an inventive role in the presently claimed invention. Accordingly, it is submitted that this publication was made by the inventors of the present application less than one year prior to the priority date of the present application (February 7, 1996), and cannot be properly cited against the application.

It is respectfully submitted that the primary reference cited by the Examiner (Diedrich et al.) does not teach or suggest the presently claimed invention.

The conclusions of the Diedrich et al article are:

1. The unwanted endogenous LH surge was avoided in all cases.
2. Only about half the amount of menotropins is required compared to the long protocol of GnRH agonists.
3. The use of GnRH antagonist Cetrorelix will be an attractive means for ovarian stimulation in the future.

4. The optimum regimen will be decided in further studies.
5. In the study, the authors were unable to reach a conclusion regarding the FSH suppression.

27 ampoules of FSH were needed per patient stimulated with HMG under Cetorelix treatment. The fertilization rate was 61.5%. In 25% of the patients the oocyte collection had to be canceled due to insufficient ovarian reaction or an endogenous LH surge. Fifteen patients were treated with 3 mg Cetorelix daily sc and five patients with 1 mg daily starting on day 7 of the menstrual cycle. This amount corresponds to 21 mg Cetorelix in one treatment period in the higher dosage group. Three pregnancies were achieved..

The present invention clearly defines an improved dosage regime during a multiple dosage regimen with only 0.1 to 0.5 mg of Cetorelix/day or a single or dual dosage in the range of preferably 2 mg to 6 mg.

The above is only a limited comparison of the teachings of the prior art reference with the present invention. Because the material is very expensive, the improved dosage is an innovative development in the method of treating infertility and is not just an optimization of the dosage amount within the expectations and capability of the ordinarily skilled artisan.

Furthermore, the Diedrich reference does not teach selective suppression of LH without affecting FSH secretion. Therefore, an advantage of the Cetrorelix treatment is that it does not affect the development of individual estrogen levels.

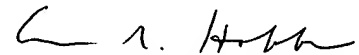
For all of the above reasons, withdrawal of the 35 USC § 103 rejection is respectfully requested.

All objections and rejections having been addressed, it is submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted

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